UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,996	05/24/2007	Mariko Fujimura	0152-0842PUS1	2104

2292 7590 11/17/2009

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
DO, PENSEE T	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
11/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

DETAILED ACTION

Priority

This application, 10587996, filed 05/24/2007 is a national stage entry of PCT/JP05/01504 , International Filing Date: 02/02/2005 and claims foreign priority to 2004-026237 , filed 02/03/2004 and has a publication number of **20080131978.**

Information Disclosure Statement

The IDS submitted on August 24, 2009 has been acknowledged and entered.

After-final Amendment Entry & Claims Status

The after-final amendment filed on October 1, 2009 has been acknowledged and entered.

Claims 1, 4-8 are pending and being examined.

Claimed Invention

1. (Currently Amended) A labeled specific binding material comprising a substance capable of specifically binding to an analyte, a spacer and magnetic beads having a diameter of [[0.1]] 0.5 to 10 um, wherein the specific binding substance is coupled to the magnetic beads via the spacer and the spacer is polyalkylene glycol having 50 to 500 repeat units.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson et al. (US PGPub. 2003/0092029 A1) in view of Rohr (US 5,445,970) and further in view of Thompson (US PGPub 2003/0190304).

Josephson teaches a composition comprising binding moieties linked to a magnetic particle. The binding moieties cause a specific interaction with a target molecule (see [58]) via functionalized polymer such as polyethylene glycol (see [24] and [61]). For claims 2-4, Josephson teaches that polymer is polyethylene glycol or polysaccharides and derivatives (see [24] and [61]). Regarding the number of repeat units, since Josephson teaches the same polymer as the present invention, such polymer must have repeat units within the same range as claimed in the present invention. For claim 6, Josephson teaches that the binding moieties are antibodies and the target analytes are antigen (see [78]). For claim 8, Josephson teaches a method of detecting a target comprising contacting such composition described above with a sample and the magnetic resonance (magnetic signal) is detected. (see [83] and [84]). Josephson teaches immobilizing polymer such as polysaccharide to the particles via biotin-avidin complex. In this embodiment, the polysaccharide has reactive ends which are biotinylated and then is exposed to avidin linked nanoparticles (see [119], [130]).

Josephson also teaches a step of washing the unbound specific binding material. (see [96] and [141]).

However, Josephson fails to teach the magnetic particles size ranges from 0.5 to 10 um (microns).

Rohr teaches using magnetic particles coated with a polymer coating as labels in assays. The magnetic particles have size range between 0.01 um to 100 um or 0.01 to 10 um (see col. 12, lines 55-65). Rohr also discusses that "as will be appreciated by those skilled in the art, the composition, shape, size and density of magnetically attractable material may vary widely and a label can be selected based upon such factors as the analyte of interest and the desired assay protocol" (see col. 12, line 65-col. 13, line 2). Rohr further suggests that "the magnetic particles can be selected to have a specific gravity so as to tend to be suspended within the reaction mixture thereby enhancing the reactivity of the binding member. The magnetic particles can also be selected to have a specific gravity so as to tend to settle in the reaction mixture thereby enhancing the reactivity of the binding member with the immobilized reagent on the solid phase. (see col. 13, lines 3-25).

Thus, it would have been obvious to one of ordinary skills in the art to combine the teaching of Rohr and Josephson to use magnetic particles size ranges from 0.5 to 10 um because particles of this size do not settle rapidly in solution as those larger than 10 um nor do they require thermal agitation as those of size smaller than 0.5 um. (see Rohr col. 13, lines 3-25). One of ordinary skills in the art would have expected

reasonable success in combining these two references because both references teach magnetic particles with polymer coating for use as labels in assays.

However, Josephson and Rohr fail to teach using a polyalkylene glycol having 50 to 500 repeat units.

Thompson teaches using a polymer such as Polyethylene gycol (PEG) as a spacer , i.e. " if two groups are linked to the polymer such as PEG, one at each end, the length of the polymer can impact upon the effective distance, and other spatial relationships, between the two groups. The polymeric portion can be of any length or molecular weight but these characteristics can affect the biological properties. Polymer average molecular weights particularly useful for decreasing clearance rates in pharmaceutical applications are in the range of [illegible] to 35,000 daltons. If the polymer is a straight chain PEG, particularly useful lengths of polymers, represented by (Z).sub.n, where Z is the monomeric unit of the polymer, include n having a range of 50-500". (See [0075]).

Since Josephson teaches using PEG as a spacer and Thompson also uses PEG as a spacer, it would have been obvious to one of ordinary skills in the art to vary the length of the PEG in Josephson to have a range of monomers from 50-500 as taught by Thompson because Thompson teaches one can vary the length of the PEG within this range of monomers to optimize or confer the desired biological activity of the two groups being linked by the PEG.

Claim 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Josephson et al. (US PGPub. 2003/0092029 A1) and further in view of Rohr and Thompson, as applied to claim 1-4, 6 and 8, and in view of Foster (US 4,444,879).

Josephson and Rohr and Thompson have been discussed above.

However, they fail to teach that the polyethylene glycol is bound to the magnetic particle via a biotin-avidin complex and packaging the composition described above into a kit.

Foster teaches packing assay reagents into a kit with instruction. (see col. 15, fig. 6).

For claim 5, although, Josephson does not explicitly teaches attaching polyethylene glycol to the surface of a magnetic particles via biotin-avidin complex, Josephson teaches a method of immobilizing a polysaccharide to a nanoparticle, such polysaccharide is used the same way as the polyethylene glycol, as a spacer or linker to bind the binding moiety to the nanoparticle. (see discussion above). Thus, one of ordinary skills in the art would be motivated to immobilize the polyethylene glycol to the nanoparticle via a biotin-avidin complex as the polysaccharide.

For claim 7, it would have been obvious to one of ordinary skills in the art to pack the reagents used in the assay taught by Josephson combined with Rohr into a kit as taught by Foster for advantage of economic convenience and long-term storage.

Response to Arguments

Applicant's arguments filed October 1, 2009 have been fully considered but they are not persuasive.

Applicants argue that Rohr does not teach that the diameter of magnetic particles may be freely selected from a range of about 0.01 to um to about 1,000 um regardless of the analyte of interest and desired assay protocol or that such a diameter may be freely applied to nanoparticles disclosed in Josephson.

This argument is irrelevant to the claimed invention because:

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the diameter of the particles may be freely selected from a range of 0.01 um to about 1,000 um regardless of the analyte of interest and desired assay protocol or that such a diameter may be freely applied to nanoparticles disclosed in Josephson) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The claimed invention is drawn to a composition and is not a method of making the composition.

Applicants further submit that Rohr implies that the particles with large diameter require being stirred in order to inhibit the settling of the particles. Applicants also submit if one of ordinary skills in the art uses magnetic particles having diameter of 0.5 to 10 um, then one of ordinary skills would expect that they must be stirred in order to inhibit settling thereof. However, the present invention does not require stirring.

Again, applicants' argument is irrelevant because the claimed invention is not drawn to a method of making the composition. Stirring is considered as a step of a

method of making the composition. Since the claims are drawn to a composition and the prior arts in the rejection teach the same composition (may be with a different method of making), these prior arts are applicable regardless of the method of making the composition.

Applicants also argue that one of ordinary skills in the art would not combine Rohr with Josephson because Josephson uses magnetic particles with small size range that does not require stirring.

However, as taught by Rohr, particles with diameter range of less than 0.03 um require thermal agitation. Rohr also teaches that the particles with size larger than 10 um respond to weak magnetic field and large particles would tend to settle rapidly. Thus, the ideal size range would be between 0.03 um and 10 um which covers the range in the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/
Examiner, Art Unit 1641

/Mark L. Shibuya/
Supervisory Patent Examiner, Art Unit 1641